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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,643 | 07/24/2006 | Giovanni Monteleone | GIU-001 | 5446 |

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| EXAMINER | |
|---|---|
| CHONG, KIMBERLY | |
| ART UNIT | PAPER NUMBER |
| 1635 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/02/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/551,643 | MONTELEONE, GIOVANNI | |
| | Examiner | Art Unit | |
| | KIMBERLY CHONG | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,20,21,23 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10,20,21,23 and 25-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The previous Restriction requirement mailed 01/22/2009 is VACATED in view of the new restriction requirement below.

*REQUIREMENT FOR UNITY OF INVENTION*

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 10, 20 and 26-29, drawn to an antisense oligonucleotide against Smad7 comprising SEQ ID No. 15 and a pharmaceutical composition comprising said antisense oligonucleotide.

Group II, claim(s) 21, 23 and 25, drawn to a method of treating inflammatory bowel disease, Crohn's disease or ulcerative colitis comprising administering an effective amount of an oligonucleotide of claim 10.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of Group I, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Steinbrecher et al. (US 20050119203 cited on PTO 872 mailed 01/22/2009), Agrawal et al. (US Patent No. 5,856,462 cited on PTO 872 mailed 01/22/2009), Krieg et al. (cited on IDS filed 09/29/2005) and Monia et al. (US Patent NO. 6,159,697 cited on PTO 872 mailed 01/22/2009).

Steinbrecher et al. teach an antisense sequence targeted to a Smad7 gene having SEQ ID NO. 10 which is identical to 20 nucleotides of the claimed sequence

(see page 39). Steinbrecher et al. teach pharmaceutical compositions (see paragraph 0107). Agrawal et al. teach the use of modified oligonucleotides that are useful for studies of gene expression and the antisense therapeutic approach and teach modification of CpG motifs in antisense oligonucleotides to modulate gene expression with reduced splenomegaly and reduced depletion of platelets (see column 2). Agrawal et al. teach modified CpG dinucleotides comprising 5-methylcytosine and further teach chimeric or hybrid oligonucleotides wherein the oligonucleotide comprises regions containing DNA as well as RNA or 2'-O-substitued RNA. Agrawal et al. further teach modification of the CpG internucleoside linkages such as methylene phosphonate (see column 6). Agrawal et al. teach pharmaceutical compositions comprising pharmaceutically acceptable carriers (see column 5). Krieg et al. teach oligonucleotides containing CpG dinucleotides trigger protective immune responses but this immune response is undesirable in antisense oligonucleotides. Krieg et al. teach the immune stimulation may be avoided in antisense oligonucleotides by the use of modified backbones and selective modifications of the cytosine nucleotides in any CpG dinucleotide. Krieg et al. teach CpG containing oligonucleotides methylated at the 5 position of the cytosine lost their immune stimulatory activities 9see page 109). Monia et al. teach antisense compounds targeted to the Smad7 gene and said antisense compounds can contain modified sugar moieties such as 2'-O-methyl modifications (see column 7) and teach antisense compounds can be from 8 to 30 nucleotides n length. It would have been obvious to modify CpG motifs in the antisense compound targeted to

Smad7 and to incorporate chemical modifications of nucleotides in the antisense compound to increase the stability of said compound.

Thus the groups of inventions listed above do not relate to a single general inventive concept

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of

the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Examiner
Art Unit 1635